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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/659,894	09/11/2003	Sebastian Vogt	100727-57/Heraeus 409-KGB	4182
27384	7590	11/13/2006	EXAMINER	
NORRIS, MCLAUGHLIN & MARCUS, PA 875 THIRD AVENUE 18TH FLOOR NEW YORK, NY 10022			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 11/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/659,894	VOGT ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 2,4-13 and 15-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date: _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date: _____   | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Whitbourne et al. (US 6,110,483), for the reasons set forth in the office action mailed 07/10/2006.

Applicant's arguments filed 10/10/2006 have been fully considered but they are not persuasive.

Applicant asserts that the Whitbourne reference is hopelessly broad and nowhere teaches a composition or subgenus containing all of these materials.

The relevance of this assertion is unclear; Whitbourne teaches a coating comprising A) antibiotic including aminoglycosides B) hydrophilic polyether polymers including PEG and C) additional hydrophobic nonionic polymers such as PVC. All of these components are listed as the ingredients for each of the three elements above therefore they are clearly taught by Whitbourne and are clearly from the disclosure combinable with one another.

Applicants assert that while Whitbourne does mention PEG it is only one of many suitable hydrophilic polymers in an exceedingly long list that includes thousands of specials in which PEG polymers are only a few. Applicant further asserts that the

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examiner has not pointed out any motivation to select PEG as opposed to some other hydrophilic polymer.

The relevance of these assertions is unclear, firstly as pointed out by the examiner in the previous office action applicants only claim a hydrophilic polymer comprising polyethers in claims 1,3 and 14 and PEG600 the elected species is not specifically claimed, therefore this claim is very broad as to what polymers would satisfy a hydrophilic polymer. Whitbourne teaches many hydrophilic polyethers such as polyethers, PEG, PEO, polysaccharides such as dextran, xanthan, HPMC and methyl cellulose (which all have ether linkages), therefore the passage within Whitbourne teaches many types of polyethers that satisfy applicants claimed invention and encompasses much more than just one polymer in thousands as stated by applicants. In regards to motivation the Whitbourne patent teaches numerous hydrophilic polymers that would satisfy applicants claimed invention, since there are numerous polyethers listed in Whitbourne there is no need for the examiner to provide motivation to use a polyether, it is inherent from the specification that polyethers are useful as hydrophilic polymers in the coating.

Applicants assert that Whitbourne does mention gentamicin free base as in example 18 and mentions gentamicin salts but teaches away from their use because of the comment that they must be converted to organic salts to be soluble in the solvents of the invention. Applicants assert that their claims require a sparingly soluble antibiotic salt.

The relevance of this assertion is unclear, firstly Whitbourne merely states that gentamicin sulfate can be converted into sodium lauryl sulfate salt, therefore it does not preclude the use of gentamicin sulfate. Even in view of this argument if it is assumed that this statement teaches away from the use of gentamicin sulfate, gentamicin lauryl sulfate salt is still a salt of gentamicin and the conversion would make the salt even more hydrophobic, thus less soluble in water than gentamicin sulfate. The disclosure as opposed to teaching away from an antibiotic salt that is insoluble in water actually teaches towards using an antibiotic which is sparingly soluble in water as claimed by applicant. In fact applicants disclose that gentamicin dodecyl sulfate (same as gentamicin lauryl sulfate) is a sparingly soluble in water antibiotic salt, see claim 2.

Applicants assert that the additional polymer (which includes PVC) is just an optional component and it is not necessary to use the additional polymer to achieve the advantage of the invention. Also applicants disclose that the additional polymer is preferably in an inner layer, which would teach against a homogenous distribution.

The relevance of these assertions is unclear, just because Whitbourne teaches that the polymers may not be necessary or optional, it is still taught that they may be used in the coating composition and therefore would not teach away from using the additional polymers such as PVC. While Whitbourne does state that the additional polymer is preferably in the inner layer to promote adhesion, the patent does not teach that it is only in the inner layer rather it is just a preferred embodiment and does not preclude a homogenous mixture. There are several physical forms for the coating encompassed within Whitbourne, one of the forms is a heterogeneous distribution of

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polymers but there are also homogenous distributions taught within the patent. In fact the coatings within Whitbourne are blends, defined as a mixture so combined as to render the components indistinguishable from each other. Such a coating is a complex structure that may have one or a combination of several physical forms. It is a coating, defined as a material that forms a thin continuous layer over the substrate, and could be referred to as a film. It may be a solid mixture of the stabilizing polymer and hydrophilic polymer or bioactive agent, additives, and possibly solvent residues blended together. Alternatively, the coating may be a complete solid solution, that is a mixture uniformly dispersed throughout the solid phase with homogeneity at the molecular or ionic level, or it may be a combination of dissolved and mixed components, such as a mixture of a polymer coating solution and insoluble particles in suspension. The coating may take the form of a composite that is a structure composed of a mixture or combination of polymer and other constituents that differ in form and chemical composition and are essentially insoluble in each other. It may be referred to as a matrix of polymer in which other components are entrapped. The coating may comprise separate layers, discrete or intermingled, each of which may have any or several of these forms. See col 4 lin 14-36. Thus Whitbourne teaches several different physical forms for the coatings, several are homogenous even with additives which would include the additional polymers, therefore the patent does not teach against homogenous distribution when an additional polymer is employed.

### ***Conclusion***

No claims are allowed at this time.

Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Michael G. Hartley", with a stylized flourish at the end.

MICHAEL G. HARTLEY  
SUPERVISORY PATENT EXAMINER